# Essential Needs and Current Gaps: Regulatory Support

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# Regulatory functions depending on vaccine source

| Regulatory functions | Vaccine source: UN agency | Vaccine source: Direct Procurement | Vaccine source: Production |
|---|---|---|---|
| Regulation System | | | |
| Licensing | | | |
| AEFI monitoring | | | |
| Lot release | | | |
| Access to laboratory | Functions assured by NRA of producing country and WHO PQ system | Fuctions assured by NRA of producing country | |
| Regulatory inspections | | | |
| Authorization of clinical trials | | | |

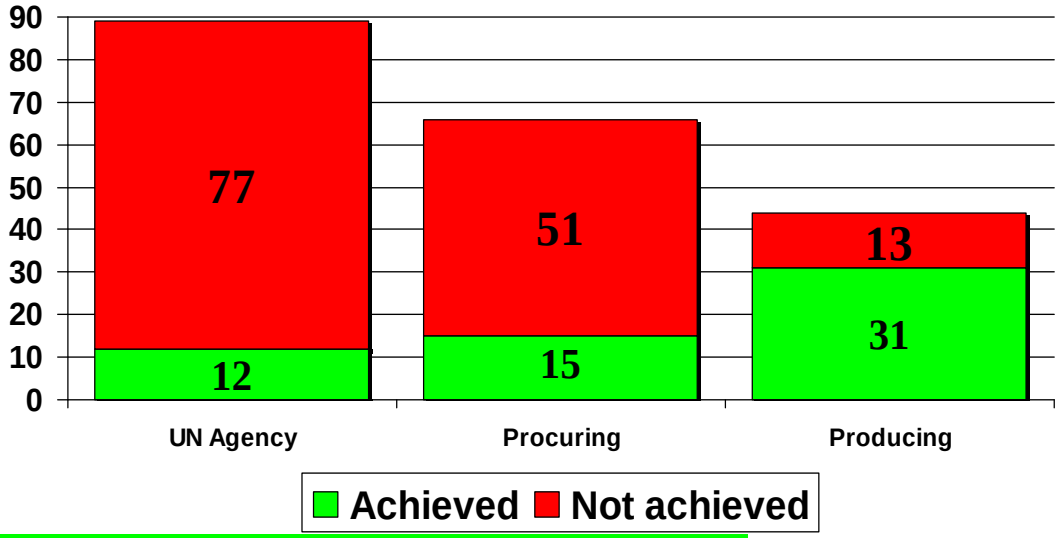
# WHO and Member States vision and stakeholder expectations

100% of vaccines used in national immunization programmes are of assured quality by 2013 (Medium Term Strategic Plan indicator)

## Partners

(UNICEF, manufacturers, GAVI, BMGF, PATH, etc)

- More and faster licensure and prequalification of vaccines




## Countries

- crisis management for vaccine safety events



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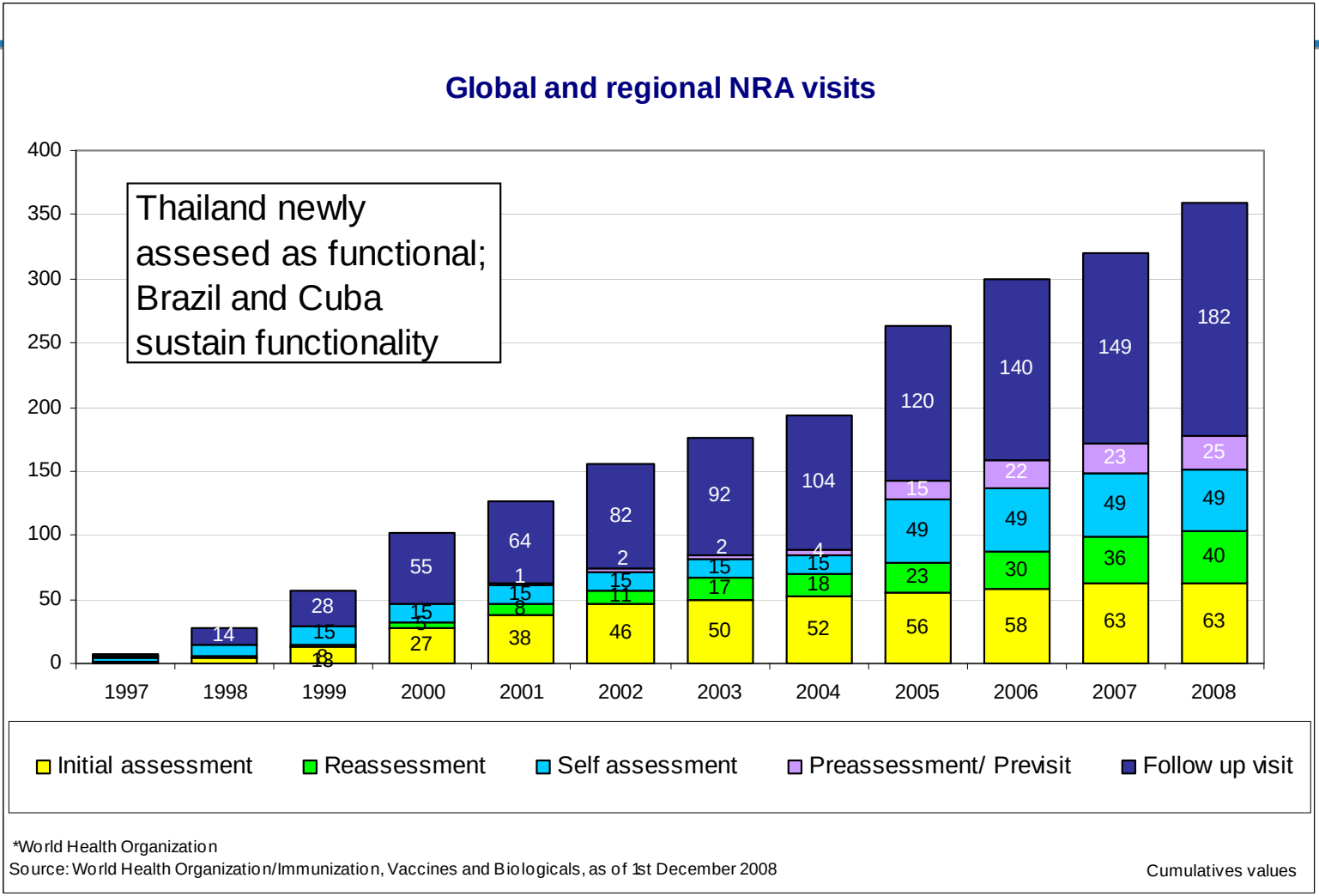
# NRA assessment activities – 2008 update




*World Health Organization

Source: World Health Organization/Immunization, Vaccines and Biologicals, as of 1st December 2008

Cumulatives values

**359 WHO* NRA VISITS CONDUCTED: 1997 – 2008**



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# Process to strengthen NRAs

## The five step capacity building programme:

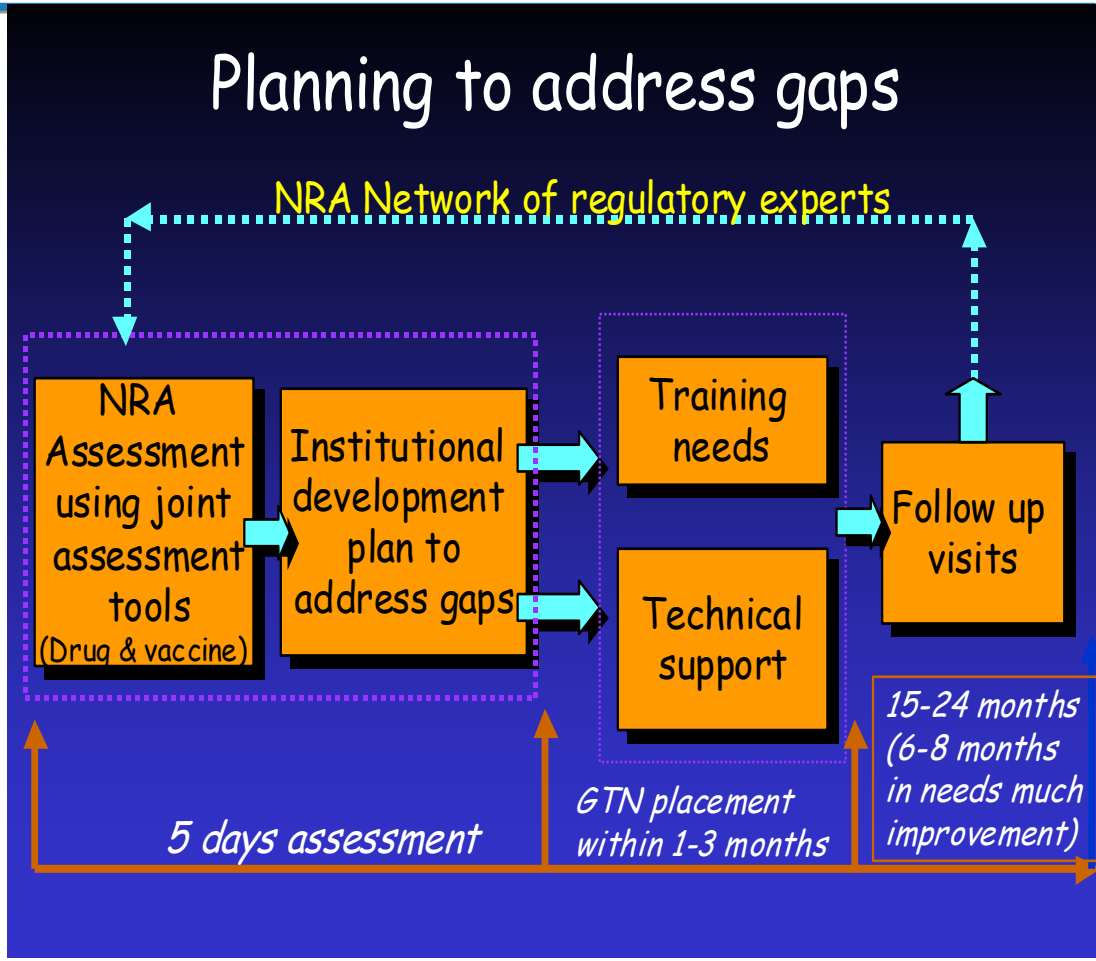
Benchmarking

NRA assessment

Planning to address gaps (**Institutional Development Plan**)

Implementation of plan, including technical inputs (GLO)

Monitoring and evaluation



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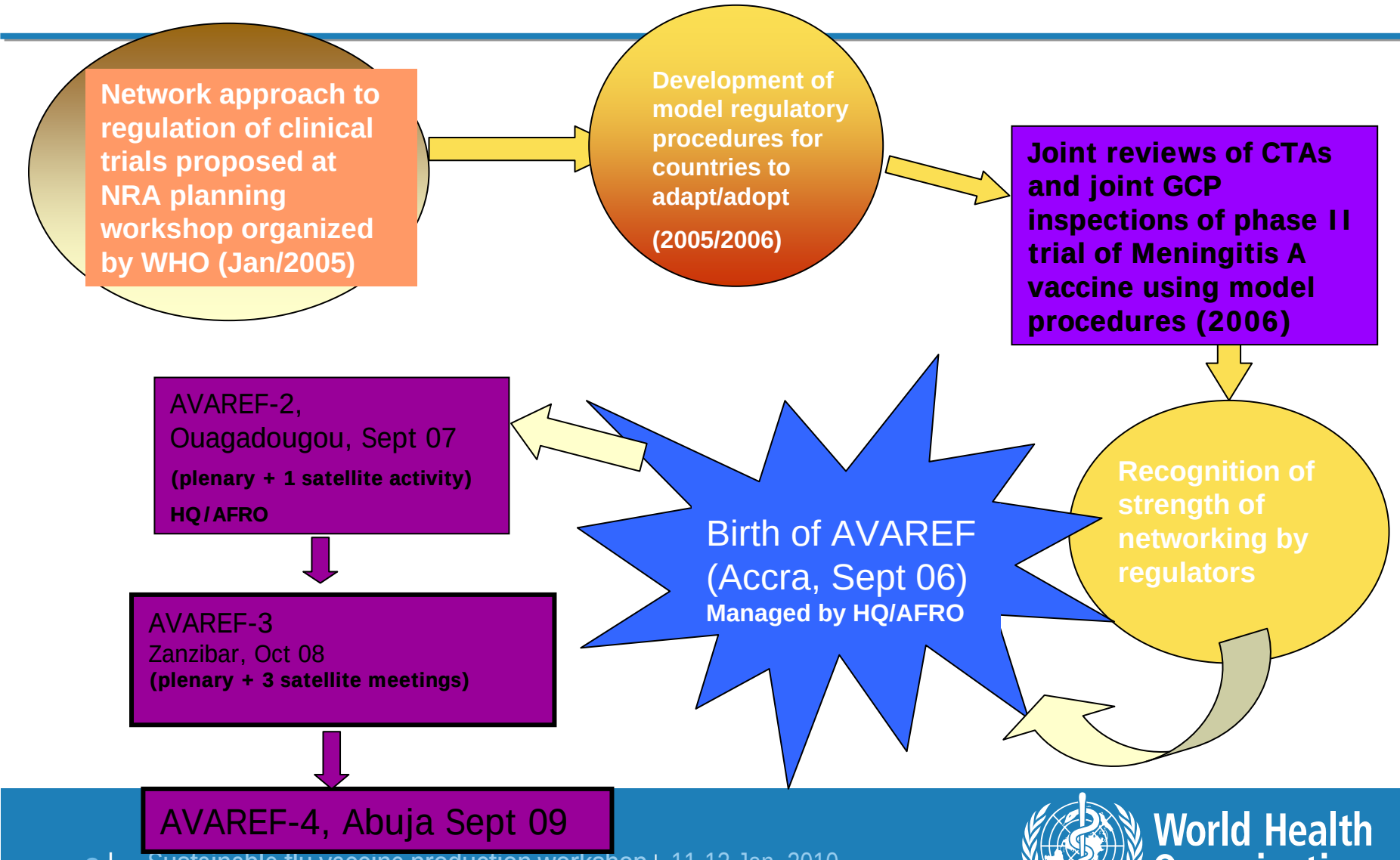
# Regulatory networking - another way to develop capacity example of AVAREF



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# AVAREF achievements


**An historical moment** : For the 1st time in Africa, regulators and ethics committee members from Burkina Faso, The Gambia, Ghana, Ethiopia and Mali conducted an inspection of Good Clinical Practice (GCP) inspection of phase ii observer-blind, randomized, active controlled clinical trial of meningococcal A conjugate vaccine at the Centre for Vaccine Development (CVD), Bamako, Mali; January, 2007



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# POST-MARKETING SURVEILLANCE OF PANDEMIC INFLUENZA A (H1N1) VACCINES

# Support being provided by WHO to countries receiving donated pandemic vaccine

- Provision of latest information on vaccine safety profile
- Definition of minimum, essential data required for a situation analysis
- Advice on format and timelines for reporting and duration of follow-up
- Provision of reporting tool, and training in it's use, by a WHO Collaborating Centre (the Uppsala Monitoring Centre) to facilitate accumulation of data locally, nationally, and to the WHO
- Access to technical advice as needed

# Conclusions

# Expansion of functional regulatory base for vaccines - lessons learned

- Influenza regulatory oversight should be embedded within an overall regulatory framework
- Strengthening regulatory agencies requires a long-term strategy and strong political commitment
- There are several ways of achieving improved regulatory capacity; whatever mechanism(s) is used it/they should be linked to an institutional development plan
- Countries have failed to develop sustainable vaccine production capacity if they have not invested in strengthening regulatory oversight in parallel with improved manufacturing facilities

# Conclusions

- Sustainable influenza vaccine production capacity requires a strong linkage of plans to develop manufacturing plant and know-how together with plans to develop independent regulatory capacity and know-how